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09/357,349 07/14/99 GEERTS

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EXAMINER

HM12/1002

TURNER, S

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ART UNIT

PAPER NUMBER

1647

7

DATE MAILED:

10/02/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/357,349

Applicant(s)

Geerts et al.

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit

1647



☒ Responsive to communication(s) filed on 6-5-00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-15 and 17-57 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-15 and 17-57 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with Sequence Rules

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

1. The preliminary amendment filed 7-14-99 has been entered into the record.
2. Claims 1-15 and 17-57 are pending.
3. On page 93 claim 46 appears twice. The second claim 46 has been renumbered claim 47 in accordance with Rule 1.26.
4. As amended claim 54 is not drawn to an antagonist. However, the examiner presumes based on applicants claim structure that their intent is for the administration of an antagonist. Claim 49 depends from claim 43. However, the examiner presumes that the claim is intended to be dependent from claim 45. The claims have been grouped accordingly. Amendment of the claims to alternative subject matter renders the claims subject to regrouping.

### ***Election/Restriction***

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, 10-14, 23 and 42-43, drawn to polynucleotides, classified in class 536, subclass 23.1.
  - II. Claims 7-9, 17-18, 24, 41 and 44 drawn to polypeptides, classified in class 530, subclass 350.
  - III. Claim 15, drawn to a transgenic cell, tissue or organism, classified in class 424, subclass 93.1.
  - IV. Claims 19-20, drawn to a method of treatment or prevention by administration of nucleic acid, classified in class 435, subclass 455.

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- V. Claims 21-22, drawn to a method of treatment or prevention by administration of a polypeptide, classified in class 424, subclass 184.1.
- VI. Claims 25-26, drawn to method of treatment or prevention by administration of cells, classified in class 424, subclass 277.1.
- VII. Claims 27-29, 30 and 40, drawn to antibody, kit, method of detection and pharmaceutical composition, classified in class 530, subclass 387.1.
- VIII. Claim 31, drawn to a method of treatment or prevention by administration of an antisense molecule, classified in class 536, subclass 24.5.
- IX. Claims 32-33, drawn to a method of identifying an agonist, classified in class 435, subclass 183.
- X. Claims 32-33, drawn to a method of identifying an antagonist, classified in class 435, subclass 174.
- XI. Claims 34, 35 and 38, drawn to an agonist, classified in class 514, subclass 73.
- XII. Claims 34, 35 and 38, drawn to an antagonist, classified in class 514, subclass 120.
- XIII. Claims 36, 52 and 53, drawn to a method of treatment using agonist, classified in class 514, subclass 92.
- XIV. Claims 37, 54 and 55, drawn to a method of treatment using antagonist, classified in class 514, subclass 128.

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- XV. Claim 39, drawn to a method for making pharmaceutical agonist, classified in class 435, subclass 68.1.
  - XVI. Claim 39, drawn to a method of making an antagonist, classified in class 435, subclass 69.2.
  - XVII. Claims 45-49, drawn to a method of identifying an agonist with an antibody specific for said signal kinase, classified in class 435, subclass 7.2.
  - XVIII. Claims 45-49, drawn to a method of identifying an antagonist with an antibody specific for said signal kinase, classified in class 435, subclass 7.9.
  - XIX. Claims 50-51, drawn to an agonist identified by the method of claim 45, classified in class 530, subclass 302.
  - XX. Claims 50-51, drawn to an antagonist identified by the method of claim 45, classified in class 530, subclass 317.
  - XXI. Claims 56-57, drawn to a method of treatment with agonist of claim 51, classified in class 514, subclass 2.
  - XXII. Claims 56-57, drawn to a method of treatment with antagonist of claim 51, classified in class 514, subclass 22.
6. The inventions are distinct, each from the other because of the following reasons:
7. Groups I-III, VII, XI-XII, and XIX-XX are related as products. The products differ each from the other in structure and function. For example, the products differ as they are differently comprised of nucleic acids, amino acids, heavy and light chains, organic molecules, inorganic

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molecules, cells, and multicellular organisms. The products function differently as they are uniquely identified by different methods, made via different processes are capable of treatment or prevention, activate or inhibit different cellular pathways and effect or block different biological responses. Thus, the products are distinct as claimed.

8. Groups IV-VI, VIII-X, XIII-XVIII, and XXI-XXII are related as processes. The processes differ each from the other in reagents, steps, and functional outcomes. For example, the processes differ as they differently comprise administration of nucleic acids, polypeptides, antibodies, cells, antisense molecules, agonists and antagonists, screen using RET activation, screen using an antibody specific for said signal kinase conjugated to a reporter, and treat or prevent disease via alternative compound administration. Thus, the processes are distinct as claimed.

9. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the process for using the nucleic acids can be practiced with polypeptide and the nucleic acids can be used in the different process of hybridization detection.

10. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the polypeptide can be practiced with nucleic acids and the polypeptide could be used in the alternative process of producing an antibody.

11. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treatment can be practiced via administration of polypeptide and the transgenic cell can be used in the different process of protein production.

12. Inventions XI and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treatment can be practiced with an alternative polypeptide and the agonist can be used in the different process of assaying for binding activity.

13. Inventions XII and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the method of treatment can be practiced with an antibody and the antagonist can be used in the different process of analyzing binding activity.

14. Inventions XIX and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the method of treatment can be practiced with an inorganic compound and the agonist can be used in a materially different process of activating T cells..

15. Inventions XX and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the method of treatment can be practiced with nucleic acid and the antagonist can be used in a materially different process of stimulating antibody production.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

17. Because these inventions are distinct for the reasons given above and the search required for each of the groups is not required for any other group, restriction for examination purposes as indicated is proper.



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18. This application contains claims directed to the following patentably distinct species of the claimed invention: receptors 1) GFR $\alpha$ 1, 2) GFR $\alpha$ 2, 3) GFR $\alpha$ 3 and 4) GFR $\alpha$ 4 and antibodies specific to 1) p42/p44 MAP kinase, 2) PKB kinase, 3) c-jun, 4) CREB, and 5) JNK/SAPIC kinase.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of receptor and antibody for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 45 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

20. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to, Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 7:30-6:00 P.M.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
September 27, 2000

*Patricia A. Duffy*  
PATRICIA A. DUFFY  
PRIMARY EXAMINER